Contracting for Research & Development (R&D) and the Emergence of the Fee-for-Service Model

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Abstract

One of the primary hurdles encountered by small, innovative companies and startups is the arduous task of advancing new technologies beyond their initial stages. Reaching commercial markets often requires access to specialized resources (i.e., complementary assets) related to R&D development and manufacturing. However, for startups investing in such resources at scale can be tremendously expensive and is often not feasible. So, do smaller innovative firms always have to relinquish the rights to valuable technologies to other industry players in control of complementary assets? The answer is no.

In our recent research, we study the biopharmaceutical industry, where startups face several challenges at the initial stage of developing and commercializing their discoveries.[1] As an example, the costs of scaling research from the lab setting for mass clinical testing can be prohibitively costly. Therefore, a common path for startup companies was to focus on developing new and innovative technologies that are then sold to larger firms that possess the resources required to advance new drugs and therapies to commercial markets.

Our research highlights an important and new alternative path toward developing and commercializing new technologies in the industry. Namely,

we document the rise of a new industry intermediary: Contract Development and Manufacturing Organizations (CDMOs). Those organizations offer access to specialized and expensive complementary assets on a *per-use* basis. This model allows firms in the industry to access those assets at early stages of the development process through an R&D fee-for-service model. With a focus on R&D services, this new business model is different from traditional contract manufacturing which tends to focus solely on mass production. Our study highlights a significant trend in the industry, wherein CDMOs have made substantial investments in complementary assets. This control has presented smaller innovative firms with an alternative pathway to advance their technologies internally and without relinquishing them to larger industry players.

A noteworthy finding of our research is that firms utilizing R&D-fee-for-service contracting can effectively mature their pipeline in-house. This enables them to maintain control over the development of their drugs for a longer duration, consequently allowing them to capitalize on the immense potential for upside profits offered by the in-house development model. Recent reports have also indicated that CDMOs are fundamentally reshaping the foundations of how biopharmaceutical companies organize their research and development activities, as well as their strategic partnerships.[2]

New R&D Strategies in the Biopharmaceutical Industry

Using quantitative data as well as insights from interviews with biopharmaceutical executives, our study found that CDMOs have continually expanded their investments in strategic complementary assets that help support the execution of clinical trials, as well as the development and mass manufacturing of new drugs and treatments. This allows firms to externalize access to highly specialized complementary assets through market contracting.

Interestingly, we observe that, with the expansion of R&D fee-for-service providers, smaller firms have started to increase their share of the total number of innovative drugs approved by the Food and Drug Administration (FDA), reaching over 60% in recent years. In contrast, in 1995, bringing new drugs on the market was dominated by the large incumbent pharmaceutical firms, at more than 80% of all approved drugs. Recent industry reports even note the proliferation of first time "launchers" in the industry, i.e., an increasing percentage of approved drugs are from firms that never had any prior drug approval.[3]

This syncs with the observation that smaller companies are gradually adjusting their business models with the goal of capturing the upside of profits from successful drug development. The substantial upside associated

with finishing a clinical trial in-house is dramatic, as one of the biotechnology CEO we interviewed noted: "*Moving from animal studies to one with 1,000 people and demonstrating an effect: The value of the clinical study is much, much higher and the payback is enormous.*" This is even more significant, considering that successful drugs have the potential to achieve $1 billion or more in sales annually. Overall, smaller biotech firms are using the R&D Fee-for-Service Model to move their own business model from providers of early stage-technologies to being able to mature their pipeline in development and even push drugs until they reach commercial markets.

Our study also uncovers that firms using the R&D-fee for service model tend to become more specialized and focused due to the higher development costs associated with in-house development. Indeed, we observe such firms to have a lower overall number of new initiations of new products in their pipeline. This signals a shift from technology supplier to technology developer and "commercializer."

We find this pattern interesting and counterintuitive: Initially one should expect that the outsourcing of R&D services through a variable cost structure would allow firms to lower costs and eventually expand their pipelines. However, R&D outsourcing, as opposed to partnering with a large company through alliances or acquisitions, still requires smaller companies to afford a substantial cost of development and commercialization, and those costs are substantial. Interestingly, we also find that firms engaging in R&D fee-for-service do not necessarily achieve more commercial success. This could alert executives of the important "value add" of larger partners, as they do due diligence if the technologies of smaller firms are economically viable.

Strategic Implications of Using the R&D fee-for-service Model

- By leveraging R&D-fee-for-service contracting, firms can internally nurture their pipeline, granting them an extended period of control over drug development. This paves the way for the realization of substantial upside profits through the in-house development model.
- Firms that adopt the R&D-fee-for-service model experience a heightened level of specialization and concentration, primarily attributed to the increased development costs incurred in the downstream phase. In fact, these firms tend to exhibit a reduced number of new product initiations within their pipeline.
- Although the implementation of the R&D fee-for-service strategy increases the chances for smaller biotech firms to preserve the potential upside of profits from in-house technology development, it does not automatically ensure a higher commercial success rate in drug launches. This observation underscores the importance of

recognizing the added value of partnering with larger industry players as viable alternative approach.

Implications

While our study is focused on the biopharmaceutical industry, R&D Fee-for-Service business models are also emerging in other contexts. For example, the contract development market in the semiconductor and electronics industry is rapidly expanding, with many organizations offering R&D and manufacturing services on a *per-use* basis.[4] Indeed, in any industry requiring highly specialized complementary assets, there may be new opportunities for intermediates to emerge. Such development is also aligned with the widespread shift towards R&D servitization models. Smaller innovative companies across industries will likely see the value in accessing the complementary assets required for the development of new technologies in-house.

However, it is important to note that the strategic implications of using the R&D fee-for-service model for smaller firms are multifaceted. Innovative companies that shift their business models from solely being early-stage developers to adopting an integrated approach, should either ensure an increased availability of resources to support this strategy or be prepared to limit the number of concurrently pursued new R&D initiatives. For these firms, it is crucial to take into account the intricacies associated with each particular R&D project. While opting for R&D fee-for-service contracting can serve as a viable approach to maintain control over potentially valuable technologies, collaborating with larger companies can heighten the prospects of commercial success in developing their technologies. Certain new R&D initiatives necessitate the expertise and resources of major industry players. Finally, as the relationship between smaller firms and CDMOs becomes more crucial, it is important to develop new skills and capabilities that allow firms to navigate this alternative R&D model. Overall, this highlights the importance of contrasting the strengths and weaknesses involved with internal development based on the R&D Fee-for-Service and the traditional partnerships with established industry players.

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Endnotes

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